REMARKS

THE AMENDMENTS AND REASONS FOR AMENDMENTS

Applicant cancels claims 84 throuth149 and submits new claims 150 through 205. The amendments add no new subject matter and are fully supported throughout the specification including the drawings and the claims as filed, for example, the Figures, Brief Description of Drawings, Page 14, and the Examples.

The amendments are made to clarify the claimed invention and to expedite the allowance of the present application. Applicant reserves the right to file later applications claiming the benefit of priority to the present application.

MAINTAINED REJECTIONS

THE PRIOR ART FAILS TO ANTICIPATE THE CLAIMED INVENTION UNDER 35 U.S.C. 102(b)

Applicant's claimed invention is novel over prior art prior to amendment. To expedite the allowance of claims, however, Applicant has canceled claims 84 through 149 and submitted new claims 150 through 204 . Applicant does so without prejudice to pursuing the original claims or related claims in another application.

The Examiner rejected claims 116, 118, 119, 126-131, 133-137, 139-143, 145, and 146 under 35 U.S.C. § 102(b) as allegedly being anticipated by Honkakoski et al. (*Mol. Cell. Biol.*, Oct. 1998). New independent claim 176, corresponding generally to canceled independent claim 116, recites a recombinant cell comprising a first nucleic acid molecule comprising a promoter or enhancer operable for a nucleic acid molecule encoding CYP3A4 operably linked to a reporter gene, and a second nucleic acid molecule comprising PXR. However, Honkakoski et al. does not teach a recombinant cell having the claimed characteristics. Each and every element of independent claim 176, and claims 177-204 that are dependent on claim 176 are not taught by Honkakoski et al. Furthermore, claims 84-149 have been cancelled, rendering this rejection moot. Thus, Honkakoski et al. does not anticipate the claims. Accordingly Applicant respectfully requests that this rejection be withdrawn.

APPLICANT'S CLAIMED INVENTION IS NOT OBVIOUS UNDER 35 U.S.C. § 103(A) IN VIEW OF THE REFERENCES CITED BY THE EXAMINER

Applicant's claimed invention is non-obvious over the prior art prior to amendment. To expedite the allowance of the application, however, Applicant has canceled all pending claims and submitted new claims. Applicant does so without prejudice to pursuing the original claims in another application.

The Examiner rejected claims 120-125. 144, and 147-149 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Honkakoski et al., in view of Iyer et al. (Eur. J. Cancer 34: 1493-1499 (1998)) and Windmill et al. (Mutation Research 376: 153-160(1997)). New independent claim 176 (which generally corresponds to canceled independent claim 116) refers to a cell comprising first and second nucleic acid molecules. The first nucleic acid molecule comprises a promoter or enhancer operable for a nucleic acid molecule encoding CYP3A4 operably linked to a reporter gene, wherein said promoter or enhancer is native to said CYP3A4, and a second nucleic acid encoding PXR. However, the cited references alone or in combination do not teach or suggest each and every element of independent claim 176. Furthermore claims 84-149 have been cancelled, rendering this rejection moot. Thus, independent claim 116 and claims 177-204 that are dependent on claim 116 are not rendered obvious by Honkakoski et al., Iyer et al., and Windmill et al. Accordingly, Applicant respectfully requests that the rejection be withdrawn.

NEW GROUNDS OF REJECTION

THE PRIOR ART FAILS TO ANTICIPATE THE CLAIMED INVENTION UNDER 35 U.S.C. 102(b)

The Examiner has rejected claims 84, 85, 92, 93, 95-101, 105-112, 116, 117, 119, 120, 126, 127, 129-135, and 139-146 under 35 U.S.C. § 102(b) as allegedly being anticipated by Quattrochi et al. (*Mol. Pharmcol., 1993*). New independent claim 150, generally corresponding to canceled independent claim 84, recites a recombinant cell comprising a first nucleic acid molecule comprising a promoter or enhancer operable for a nucleic acid molecule encoding CYP3A4 operably linked to a reported gene, and a second nucleic acid molecule comprising PXR, wherein

said first nucleic acid molecule, said second nucleic acid molecule, or both, are stably transfected into said recombinant cell. However, Quattrochi et al. does not teach a recombinant cell having the claimed characteristics. Each and every element of independent claim 150, and claims 151-181 that are dependent on claim 150 are not taught by Quattrochi et al. Furthermore, claims 84-149 have been cancelled, rendering this rejection moot. Thus, Quattrochi et al. does not anticipate the claims. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

The Examiner rejected claims 116, 118, 119, 126-128, 131, 133-143, 145, and 149 under 35 U.S.C. § 102(b) as allegedly being anticipated by Klierwer et al. (*Cell, 1998*). New independent claim 176, generally corresponding to canceled independent claim 116, recites a recombinant cell comprising a first nucleic acid molecule comprising a promoter or enhancer operable for a nucleic acid molecule encoding CYP3A4 operably linked to a reported gene, and a second nucleic acid molecule comprising PXR. However, Klierwer et al. does not teach a recombinant cell having the claimed characteristics. Each and every element of independent claim 176, and claims 177-204 that are dependent on claim 176 are not taught by Klierwer et al. Furthermore, claims 84-149 have been cancelled, rendering this rejection moot. Thus, Honkakoski et al. does not anticipate the claims. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

APPLICANT'S CLAIMED INVENTION IS NOT OBVIOUS UNDER 35 U.S.C. § 103(A) IN VIEW OF THE REFERENCES CITED BY THE EXAMINER

The Examiner rejected claims 84-115, 117, 128-130, 132, 138, and 139 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Honkakoski et al., in view of Iyer et al. (Eur. J. Cancer 34: 1493-1499 (1998)) and Windmill et al. (Mutation Research 376: 153-160(1997)), and further in view of Makrides (*Protein Expr. Purif., 1999*). New independent claim 150 (which generally corresponds to canceled independent claim 84) refers to a cell comprising first and second nucleic acid molecules. The first nucleic acid molecule comprises a promoter or enhancer operable for a nucleic acid molecule encoding CYP3A4 operably linked to a reporter gene, wherein said promoter or enhancer is native to said CYP3A4, and a second nucleic acid encoding

PXR. However, the cited references alone or in combination do not teach or suggest each and every element of independent claim 150. Furthermore, claims 84-149 have been cancelled rendering this rejection moot. Thus, independent claim 150 and claims 151-175 that are dependent on claim 150 are not rendered obvious by Honkakoski et al., Iyer et al., Windmill et al., and Makrides. Accordingly, Applicant therefore respectfully requests that the rejection be withdrawn.

The Examiner rejected claims 86-91, 113-115, 120-125, and 147-149 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Quattrochi et al. (*Mol. Pharmcol., 1993*), in view of Iyer et al. (Eur. J. Cancer 34: 1493-1499 (1998)) and Windmill et al. (Mutation Research 376: 153-160(1997)). New independent claim 150 (which generally corresponds to canceled independent claim 84) refers to a cell comprising first and second nucleic acid molecules. The first nucleic acid molecule comprises a promoter or enhancer operable for a nucleic acid molecule encoding CYP3A4 operably linked to a reporter gene, wherein said promoter or enhancer is native to said CYP3A4, and a second nucleic acid encoding PXR. However, the cited references alone or in combination do not teach or suggest each and every element of independent claim 150. Furthermore, claims 84-149 have been cancelled rendering this rejection moot. Thus, independent claim 150 and claims 151-175 that are dependent on claim 150 are not rendered obvious by Quattrochi et al., Iyer et al., and Windmill et al. Accordingly, Applicant therefore respectfully requests that the rejection be withdrawn.

The Examiner rejected claims 120-125, 144, and 146-148 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Klierwer et al. (*Cell, 1998*), in view of Iyer et al. (Eur. J. Cancer 34: 1493-1499 (1998)) and Windmill et al. (Mutation Research 376: 153-160(1997)). New independent claim 176 (which generally corresponds to canceled independent claim 116) refers to a cell comprising first and second nucleic acid molecules. The first nucleic acid molecule comprises a promoter or enhancer operable for a nucleic acid molecule encoding CYP3A4 operably linked to a reporter gene, wherein said promoter or enhancer is native to said CYP3A4, and a second nucleic acid encoding PXR. However, the cited references alone or in combination do not teach or suggest each and every element of independent claim 176. Furthermore, claims

84-149 have been cancelled rendering this rejection moot. Thus, independent claim 176 and claims 177-204 that are dependent on claim 176 are not rendered obvious by Kliewer et al., Iyer et al., and Windmill et al. Accordingly, Applicant therefore respectfully requests that the rejection be withdrawn.

The Examiner rejected claims 84-115, 117, 129, 130, and132 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Klierwer et al. (*Cell, 1998*), in view of Iyer et al. (Eur. J. Cancer 34: 1493-1499 (1998)) and Windmill et al. (Mutation Research 376: 153-160(1997)), and further in view of Makrides (*Protein Expr. Purif., 1999*). New independent claim 150 (which generally corresponds to canceled independent claim 84) refers to a cell comprising first and second nucleic acid molecules. The first nucleic acid molecule comprises a promoter or enhancer operable for a nucleic acid molecule encoding CYP3A4 operably linked to a reporter gene, wherein said promoter or enhancer is native to said CYP3A4, and a second nucleic acid encoding PXR. Honkakoski et al. demonstrates the use of cells transiently transfected with nucleic acid constructs. However, the cited references alone or in combination do not teach or suggest each and every element of independent claim 150. Claims 84-149 have been cancelled rendering this rejection moot. Thus, independent claim 150 and claims 151-175 that are dependent on claim 150 are not rendered obvious by Kliewer et al., Iyer et al., Windmill et al., and Makrides. Accordingly, Applicant therefore respectfully requests that the rejection be withdrawn.

Applicant respectfully submit that the claims are ready for examination and in condition for allowance.

Please apply any charges not covered, or any credits, to **Deposit Account Number 501321** in the name of David R. Preston & Associates, having **Customer Number 24232**.

Respectfully submitted,

Date: June 17, 2004

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